signee. The repackaged tablets would be dangerous to health when used according to directions. The labeling of both lots of tablets failed to bear adequate warning statements and satisfactory ingredient statements. Furthermore, the labeling of the bulk tablets failed to bear directions for use, and that of the repackaged tablets also bore false and misleading therapeutic claims.

On June 7, 1941, the United States attorney for the District of Maryland filed a libel against the above-named products at Baltimore, Md., alleging that they had been shipped on or about February 24 and 26 and March 4 and 10, 1941, by Sharp & Dohme from Philadelphia, Pa., and that having been so shipped, they remained in interstate commerce on the premises of the Read Drug & Chemical Co. at Baltimore, Md.; and charging that they were misbranded. The bulk tablets were labeled in part: (Container) "Sharp & Dohme Philadelphia, Pa. * * * No. 48511–C Made for Read Drug & Chemical Co. Baltimore, Md."

Analyses of samples taken from the bulk containers and the retail cartons showed that each tablet contained acetanilid (approximately 2 grains), quinine sulfate (¼ grain), podophyllin, capsicum, and belladonna extract.

The repackaged tablets were alleged to be misbranded: (1) In that they would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, namely, "Adults: 1 tablet every 4 hours until bowels move freely, then 1 tablet 2 or 3 times daily," since if taken in accordance with such directions they might result in the patient's ingesting amounts of acetanilid that would be dangerous to health. (2) In that the name "Goodwin's Laxative Cold Tablets" and the statements "Effective in the Treatment of Colds. Relieves the Feverish Condition which Accompany Colds," and "Keeps the Bowels Active," appearing in the labeling, were false and misleading since they gave the impression that the article was an effective treatment for colds; whereas it was not an effective treatment for colds and would not fulfill the promises of benefit made and implied by such statements. (3) In that a quantity of belladonna alkaloids was present in the article and the labeling did not bear a statement of the quantity or proportion of the belladonna alkaloids present.

Both lots of tablets were alleged to be misbranded in that the labeling did not bear adequate warnings against use in those pathological conditions or by children where their use might be dangerous to health and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users, since said labeling bore no warnings that their use should be discontinued if a skin rash appeared; that they should be used cautiously if dryness of the throat occurred; that their use should be discontinued if rapid pulse or blurring of the vision resulted; that the preparation should not be taken by children; that frequent or continued use might be dangerous to health by causing serious blood disturbances, anemia, collapse, or dependence on the drug; that the preparation should not be taken by elderly people except on competent advice; that frequent use of the preparation might lead to dependence upon laxatives to move the bowels; and (bulk tablets only) since said labeling did not carry a warning against use of the article in the presence of abdominal pain, nausea, vomiting, or other symtoms of appendicitis.

The bulk tablets were alleged to be misbranded further (1) in that the label failed to bear adequate directions for use since it did not bear any directions for use; and (2) in that the labeling did not bear the common or usual name of each active ingredient, namely, acetanilid, quinine sulfate, podophyllin, capsicum, and belladonna extract, and in that it did not bear a statement of the quantity or proportion of acetanilid and belladonna extracts.

On August 6, 1941, the Read Drug & Chemical Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be repackaged and relabeled under the supervision of the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS[1]

660. Misbranding of acetylsalicylic acid and colchicine compound capsules. U. S. v. Sam Frank Drug Co. Plea of guilty. Fine, $10. (F. D. C. 6430. Sample No. 65040–E).

In addition to failure to bear adequate warning statements, the label of this product failed to bear the required ingredient statement.

On March 13, 1942, the United States attorney for the District of Colorado filed an information against the Sam Frank Drug Co., a corporation at Denver,

[1] See also Nos. 657, 659.

Colo., alleging that within the period from on or about February 13 to on or about May 8, 1941, the defendant had repacked and relabeled quantities of the above-named product while it was being held for sale after shipment in interstate commerce, which acts by the defendant resulted in misbranding of said drug. At the time of shipment the product was labeled: "5000 Capsules Acetylsalicylic Acid and Colchicine Compound (Formerly Called Roomatoan) Brown. Each capsule contains: Acetylsalicylic Acid . . . 5 grs. Macrotin . . . ¼ gr. Phytolaccin . . . ⅛ gr. Colchicine . . . 1/300 gr. Caution: These capsules are to be used only by or on the prescription of a physician." After repackaging and relabeling it was labeled: "One Capsule Every hour for 4 doses Then One Every 4 hours Sam Frank Drug Co. Colfax at Downing—Denver Keystone 3217."

The article when repacked and relabeled was misbranded: (1) In that it contained colchicine, the frequent or continued use of which might result in abdominal pain (stomach ache, cramps, colic), nausea, vomiting, diarrhea, or bloody urine, and in that the statements on the label failed to bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users. (2) In that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient.

On March 16, 1942, the defendant entered a plea of guilty and the court imposed a fine of $10.

661. Misbranding of Nichol's Long Life For Health and Dickson's Laxative Diuretic. U. S. v. James B. Nichols (J. B. Nichols & Sons and Nichols Chemical Co.). Plea of guilty. Fine of $100 and jail sentence of 6 months. Sentences suspended and defendant placed on probation for 3 years. (F. D. C. No. 5475. Sample Nos. 39561–E, 39562–E.)

The labeling of the Laxative Diuretic failed to bear adequate warning statements; that of both products bore false and misleading therapeutic claims and inadequate ingredient and quantity of contents statements. The bottles containing both products were paneled in such manner as to be deceptive.

On January 26, 1942, the United States attorney for the Western District of Tennessee filed a libel against James B. Nichols, trading as J. B. Nichols & Sons, and as Nichols Chemical Co. at Memphis, Tenn., alleging shipment on or about November 12, 1940, from the State of Tennessee into the State of Arkansas of quantities of the above-named products that were misbranded.

Analyses of samples of the products showed that Nichol's Long Life for Health consisted of extracts of plant drugs, alcohol (13.0 percent by volume), and water; and that Dickson's Laxative Diuretic consisted essentially of Epsom salt, small proportions of caramel, methenamine, hysocyamine, salicyclic acid, sulfuric acid, and benzoic acid, minute amounts of strychnine and saccharin, and water.

Dickson's Laxative Diuretic was alleged to be misbranded: (1) In that its labeling did not bear adequate warnings against use in those pathological conditions where its use might be injurious to health or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users, since its labeling did not bear a warning that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use might result in dependence on laxatives. (2) In that statements appearing on the bottle label which represented that each bottle contained 8 ounces of the drug, that it was efficacious as an aid in eliminating and correcting disorders of the alimentary canal and urinary organs, and that it would be efficacious in the treatment of biliousness, headache, gas on the stomach, and backache, were false and misleading since each bottle did not contain 8 ounces of the drug, but did contain a smaller amount, it was not efficacious as an aid in eliminating or correcting disorders of the alimentary canal or urinary organs and it would not be efficacious in the treatment of biliousness, gas on the stomach, or backache. (3) In that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, including the quantity or proportion of hyoscyamine and strychnine, since (a) the declaration of "hyeciamus" was meaningless; (b) the label bore no statement of the quantity or proportion of strychnine; and (c) it failed to bear the common or usual name of methenamine since the designation "Utropian," appearing on the label, is not the common or usual name of methenamine. (4) In that it was in package form and the labeling failed to bear an accurate statement of the quantity of contents in terms of measure. (5) In that its container (bottle) was so made and formed as to be misleading.

Nichol's Long Life for Health was alleged to be misbranded: (1) In that statements on the bottle label representing that it would be efficacious to prolong